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EUROPEAN PRECIOUS METALS FEDERATION
FOR INFORMATION

19 December 2014

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: FYI Processing
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
UNITED STATES

Dear Sir/Madam,

RE: For Your Information: Potassium Dicyanoaurate (CAS number: 13967-50-5)

The European Precious Metals Federation on behalf of its members is providing information on the *in vitro* Micronucleus Assay on Human Lymphocytes with Potassium Dicyanoaurate (CAS number: 13967-50-5).

It is considered that the study outcome on its own is not supportive of a conclusion of substantial risk. The mutagenic potential of soluble cyanide salts has been previously characterised in existing literature and concluded on the absence of mutagenic, carcinogenic or teratogenic properties.
Based on industrial experience no cause-effect relation can be suspected between the exposure to the substance and mutagenic consequences. An *in vivo* micronucleus assay, now required per the REACH Regulation, will confirm if this test outcome is a false positive.

An *in vitro* Micronucleus Assay on Human Lymphocytes (HLM) with Potassium Dicyanoaurate has been conducted under the direction of the Precious Metals and Rhenium Consortium c/o European Precious Metals Federation aisbl (PMC c/o EPMF), Brussels, Belgium as part of the integrated testing strategy developed to fulfil the information requirements for the classification and labelling notification and REACH Registration Dossier of the above substance under Directive 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Directive 2008/112/EC of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP).

The study conformed to the requirements of OECD Guideline 487. In this study Potassium Dicyanoaurate (CAS number: 13967-50-5) showed evidence of toxicity and induced statistically significant increases in the frequency of cells with micronuclei, in all three exposure groups, using a dose range that included a dose level which approached the 60% reduction in CBPI. These increases

~ *a member of Eurometaux* ~
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23
e-mail: info@epmf.be **website:** www.epmf.be

exhibited a dose-response relationship. As a result, the test item should be considered mutagenic under the condition of this test. An *in vivo* Micronucleus Assay, OECD Guideline 474, will be conducted according to Annexes VIII and IX of the REACH Regulation, that will confirm or infirm this outcome.

These findings are not congruent with some previously published reports on mutagenic effects investigations determined in various experimental toxicology studies on soluble cyanide compounds: several publications are reporting the absence of mutagenic effects of soluble cyanides. These findings are also not congruent with workplace observations: no cause relation has ever been suspected between the substance and gene alterations related sickness of workers. Therefore EPMF does believe that the study outcome is a false positive and does not believe that this information is supportive of a conclusion of "substantial risk" within the definitions of TSCA Section 8(e). However, the submitter considers that the test outcome improves the overall knowledge base in this area, and hence EPMF is voluntarily sharing it with EPA on a FYI basis. This submission should therefore discharge any Section 8(e) responsibilities that might exist, and can be processed in accordance with EPA's procedures.

This FYI Submission will be updated with the results of the future OECD Guideline 474, *in vivo* micronucleus assay.

If you have any questions, please contact:

Renaud Nicolay
REACH & CLP Manager
PMC c/o EPMF
Avenue de Broqueville 12, B-1150 Brussels, BELGIUM
+32 2 775 63 85
renaud.nicolay@epmf.be
Cc. info@epmf.be

Sincerely,

David Boyd
Interim Trustee
European Precious Metals Federation
Avenue de Broqueville 12, B-1150 Brussels, BELGIUM

~ *a member of Eurometaux* ~
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23
e-mail: info@epmf.be **website:** www.epmf.be

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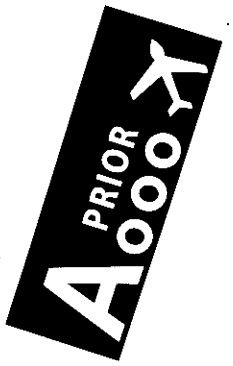
USA



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European Precious Metals Federation
Avenue de Broqueville 12, B-1150 Bruxelles

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